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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/942,055	08/29/2001	Robert Powers	16163-021002	8112
26161	7590	09/21/2004	EXAMINER	
FISH & RICHARDSON PC 225 FRANKLIN ST BOSTON, MA 02110			MAHATAN, CHANNING	
			ART UNIT	PAPER NUMBER
			1631	

DATE MAILED: 09/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/942,055

Applicant(s)

POWERS ET AL.

Examiner

Channing S Mahatan

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 June 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10-16, 18, 20-24, 26-29, 33-37 and 45-66 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10-16, 18, 20-24, 26-29, 33-37, and 45-66 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 August 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>4 Sheets</u> . | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1631

DETAILED ACTION

APPLICANTS' ARGUMENTS

Applicants' arguments, filed 28 June 2004, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application. It should be noted the rejection under 35 U.S.C. § 103 (a) is withdrawn based on the claim amendments.

CLAIMS UNDER EXAMINATION

Claims herein under examination are claims 10-16, 18, 20-24, 26-29, 33-37, and 45-66.

Claims 1-9, 17, 19, 25, 30-32, and 38-44 have been cancelled.

Claim Rejected Under 35 U.S.C. § 101

35 U.S.C. § 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

NON-STATUTORY SUBJECT MATTER

Claim 18 is rejected under 35 U.S.C. § 101 because the claimed invention is directed to non-statutory subject matter. The claimed invention is directed to a "process", wherein only the step of determining the interaction between a candidate species and a free RGS protein using a three-dimensional structure of a polypeptide including at least a core region of a free RGS4 protein" is indicated.

M.P.E.P. section entitled "Nonstatutory Subject Matter" (pages 2100-12, Columns 1-2) states:

Claims to processes that do nothing more than solve mathematical problems or manipulate

Art Unit: 1631

abstract ideas or concepts are more complex to analyze and are addressed below.

If the “acts” of a claimed process manipulate only numbers, abstract concepts or ideas, or signals representing any of the foregoing, the acts are not being applied to appropriate subject matter. Schrader, 22 F.3d at 294-95, 30 U.S.P.Q.2d at 1458-59. Thus, a process consisting solely of mathematical operations, i.e., converting one set of numbers into another set of numbers, does not manipulate appropriate subject matter and thus cannot constitute a statutory process.

Further, M.P.E.P. section entitled “Statutory Process Claims” (page 2100-15, Column 1-2) states:

A claim that requires one or more acts to be performed defines a process. However, not all processes are statutory under 35 U.S.C. 101. Schrader, 22 F.3d at 296, 30 U.S.P.Q.2d at 1460. To be statutory, a claimed computer-related process must either: (A) result in a physical transformation outside the computer for which a practical application in the technological arts is either disclosed in the specification or would have been known to a skilled artisan (discussed in i) below), or (B) be limited to a practical application within the technological arts (discussed in ii) below). See *Diamond v. Diehr*, 450 U.S. at 183-84, 209 U.S.P.Q. at 6 (quoting *Cochrane v. Deener*, 94 U.S. 780, 787-88 (1877)) (“A [statutory] process is a mode of treatment of certain materials to produce a given result. It is an act, or a series of acts, performed upon the subject-matter to be transformed and reduced to a different state or thing.... The process requires that certain things should be done with certain substances, and in a certain order; but the tools to be used in doing this may be of secondary consequence.”). See also *Alappat*, 33 F.3d at 1543, 31 U.S.P.Q.2d at 1556-57 (quoting *Diamond v. Diehr*, 450 U.S. at 192, 209 U.S.P.Q. at 10). See also *id.* at 1569, 31 U.S.P.Q.2d at 1578-79 (Newman, J., concurring) (“unpatentability of the principle does not defeat patentability of its practical applications”) (citing *O'Reilly v. Morse*, 56 U.S. (15 How.) at 114-19). If a physical transformation occurs outside the computer, a disclosure that permits a skilled artisan to practice the claimed invention, i.e., to put it to a practical use, is sufficient. On the other hand, it is necessary for the claimed invention taken as a whole to produce a practical application if there is only a transformation of signals or data inside a computer or if a process merely manipulates concepts or converts one set of numbers into another.

The process of claim 18 is viewed as merely a “mental” process of performing mathematical operations (manipulation of numbers). Absent from the instant claims are any indication of what the determined information represents (other than a general interaction) and what one is to do with the obtained information. In the absence of what the information is for and what one is to do with such information, no concrete, tangible, or useful result is obtained by the claimed method.

Claims Rejected Under 35 U.S.C. § 112 1st Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Art Unit: 1631

NEW MATTER

Claims 10-16, 18, 20-24, 26-29, 33-37, and 45-66 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 10, 18, 20, 23, 26, 28, and all claims dependent therefrom are rejected under 35 U.S.C. § 112, first paragraph. The amendment(s) of “a polypeptide including at least a core region of a free RGS4 protein” is considered new matter. There does not appear to be support for such broadly encompassing limitations of all “polypeptides including at least a core region of a free RGS4 protein”. For example, such language is interpreted to imply a core region of a free RGS4 protein with any number and type of polypeptides flanking it, wherein such support cannot be found (Refer to below 35 U.S.C. § 112 1st Paragraph Rejection). Therefore, the above amendments are considered NEW MATTER.

SCOPE OF ENABLEMENT

Claims 10-16, 18, 20-24, 26-29, 33-37, and 45-66 are rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for the three-dimensional coordinates of “regulators of G-protein signaling-4” (RGS4; listed in Table 2), does not reasonably provide enablement for all three-dimensional coordinates of polypeptides including at least a core region of a free RGS4. This rejection is maintained for reasons of record, in view of amendments to the instant claims. Applicants have presented arguments in a Wands type fashion and is addressed herein.

Art Unit: 1631

The nature of the invention

Applicant asserts the nature of the invention relates to the use of a three-dimensional structure of a polypeptide including at least a core region of a free RGS4 protein, which is agreed with.

The level of one of ordinary skill

Applicants assert the level of one of ordinary skill in the art would likely have a B.S. or a Ph.D. in biology (i.e. protein biology), which is agreed with.

The state of the prior art

Applicants assert no one has previously disclosed or suggested the methods covered by the pending claims, this is agreed with.

The breadth of the claims

Applicant asserts the breadth of the instant claims is no broader than Applicants' contribution. This is disagreed with on the grounds that the instant claims recite the limitation "polypeptides including at least a core region of a free RGS4 protein" which broadly encompasses all polypeptides including at least a core region of a free RGS4 protein that are not taught (Refer to above 35 U.S.C. § 112 1st Paragraph 'New Matter' Rejection).

(E) The level of predictability in the art

Applicant asserts the relevant art is generally unpredictable, which is agreed with.

The existence of working examples

Applicant asserts the present specification provides: 1) a working example that describes the determination of the three-dimensional structure of the core region of the RGS4, as well as the identification of allosteric binding site in the core region of RGS4; and 2) describes assays

Art Unit: 1631

that test for modulators of RGS4 binding to $G_{\alpha i1}$ and modulators of RGS4 GTPase activity.

While this is agreed with, the provided examples are not representative of all that the instant claims presently embrace. The working examples do not provide methodologies and/or processes by which one of skill in the art is to derive all other three-dimensional coordinates of “polypeptides including at least a core region of a free RGS4 protein”.

The amount of direction provided by the inventor

Applicant asserts the application provides sufficient direction to one of ordinary skill in the art. However, this is disagreed with wherein the specification is devoid of any teaching beyond the three-dimensional coordinates of “regulators of G-protein signaling-4) (RGS4; listed in Table 2). Absent is the manner/procedures the one of skill in the art would derive all other three-dimensional coordinates of “polypeptides including at least a core region of a free RGS4 protein”. Again, in such absence one of skill in the art would be required to perform further undue experimentation to derive the three-dimensional coordinates of all other said polypeptides.

The quantity of experimentation needed to make or use the invention based on the content of the disclosure

In the absence of adequate guidance and working examples by which to derive all other three-dimensional coordinates of “polypeptides including at least a core region of a free RGS4” one of skill in the art would be required to utilize inventive skill for such derivation by identifying or designing “polypeptides including at least a core region of a free RGS4” through the formulation of independent decisions and judgements about the criteria(s)/parameter(s) (i.e. flanking polypeptides), and to test & validate these derived polypeptides. Such independent decisions, judgments, tests, & validation are not routine and is considered undue

Art Unit: 1631

experimentation. Applicants are directed to *Fields, Wilkinson, and Kende v. Conover* and *Woodward* [170 USPQ 276; How-to-Make Requirement section] which states:

"the description must place the invention in the possession of the public as fully as if the art or instrument itself had been practically and publicly employed. In order to accomplish this, it must be so particular and definite that from it alone, without experiment or the exertion of his own inventive skill, any person versed in the art to which it appertains could construct and use it."

Therefore, in view of the deficiencies as addressed above one of skill in the art would be unable to derive all three-dimensional coordinates of "polypeptides including at least a core region of a free RGS4". Thus, the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Claims Rejected Under 35 U.S.C. § 112 2nd Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 10-16, 18, 20-24, 26-29, 33-37, and 45-66 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

VAGUE AND INDEFINITE

Claims 10-12, 14, 18, 19, 21, 22, 24, and all claims dependent therefrom recite the limitation "interaction"/"predicted by its interaction"/"predicted interaction"/"interact" which is vague and indefinite. Applicants argue that these terms would be readily understood by one skilled in the art and provide the following definition citing (Merriam-Webster's Collegiate Dictionary, 10th Edition, Merriam-Webster, Incorporated, Springfield, MA, 1997 at 609):

- 1) interact is defined as "to act upon one another"; and
- 2) interaction is defined as "mutual or reciprocal action or influence".

Art Unit: 1631

This is found unpersuasive. For example, referring to claim 10 the selection of a potential modulator of an RGS protein is indicated as being based upon the interaction. What is criteria(s)/parameter(s) for the selection of a potential modulator in the in view of Applicants' provided definition? In the absence of criteria(s)/parameter(s), which characterizes the "based upon" interaction, it is unclear what is to be selected. Further, water (chemical or biochemical test species) may be considered to interact given the definition above, however, it is unclear if Applicants intend water to be encompassed by the instant claims in the absence of specific identifiable characteristics of the interaction. If it is Applicants' intent that "interact"/"interaction" is the equivalent to "will bind to"/"binds to" (i.e. claims 33, 34, etc.), this is not apparent. Clarification of the metes and bounds, via clearer claim language, is requested.

Claim 10 and claims dependent therefrom are indefinite due to the lack of clarity of the claim language. The preamble states that it is "A method...", however, the final step of claim 10 recites the step of "selecting a potential modulator of an RGS protein" whereas the claim 16 provides the "further comprising" language indicated the final step of "assaying the potential modulator to measure its activity as a modulator". Thus, it is unclear what method Applicants' intend the instant claims to be directed to; either a method of selecting a potential modulator of an RGS protein or a method of measuring the activity of a potential modulator as a modulator of an RGS protein. Clarification of the metes and bounds of the claim is requested, via clearer claim wording.

Claim 18 recites only the step of "determining the interaction between a candidate species and a free RGS protein using a three-dimensional structure of a polypeptide including at least a core region of a free RGS4 protein" which is considered vague and indefinite. For

Art Unit: 1631

example, once some unclear interaction is determined what does the information mean? What is an individual of ordinary skill in the art to do with the information? No further steps are provided. Clarification of the metes and bounds, via clearer claim language, is requested.

Claims 28, 37, and claims dependent therefrom are indefinite due to the lack of clarity of the claim language. The preamble states that it is "A method...", however, the final step of claim 28 recites the step of "synthesizing or otherwise obtaining the potential antagonist or agonist" whereas the claim 37 provides the "further comprising" language indicated the final step of "testing the potential antagonist or agonist as a modulator of RGS protein activity, RGS binding, or RGS-GA complex activity". Thus, it is unclear what method Applicants' intend the instant claims to be directed to; either a method of synthesizing or a method of obtaining or a method of testing. Clarification of the metes and bounds of the claim is requested, via clearer claim wording.

INFORMATION DISCLOSURE STATEMENT

The 'Information Disclosure Statement' (filed 26 April 2004) references de Alba et al., which has been lined through because it appears as duplication of a previously cited reference. The reference was previously cited by the Examiner in the PTO-892 form (mailed 24 March 2004).

No Claims Are Allowed.

ACTION IS FINAL, AS NECESSITATED BY AMENDMENT

Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See M.P.E.P. § 706.07(a). Applicants are reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

Art Unit: 1631

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. § 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

EXAMINER INFORMATION

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 C.F.R. § 1.6(d)). The CM1 Fax Center number is either (703) 872-9306.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Channing S. Mahatan whose telephone number is (571) 272-0717. The Examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward, Ph.D., can be reached on (571) 272-0722.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Art Unit: 1631

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify Applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables Applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Date:

September 16, 2004

Examiner Initials:

CSM

Marianne P. Allen
MARIANNE P. ALLEN
PRIMARY EXAMINER
9/16/04
AU 1631